UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

ADAM KANUSZEWSKI, et al.,

Plaintiffs,

Case No. 18-cv-10472

v.

Honorable Thomas L. Ludington

SANDIP SHAH, et al.,

Defendants.
_____/

OPINION AND ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT, GRANTING IN PART AND DENYING IN PART STATE DEFENDANTS' MOTION FOR SUMMARY JUDGMENT, GRANTING IN PART AND DENYING IN PART DEFENDANT YANCEY'S MOTION FOR SUMMARY JUDGMENT, DENYING PLAINTIFFS' MOTION FOR LEAVE TO FILE EXHIBIT IN THE TRADITIONAL MANNER, AND DIRECTING PLAINTIFFS TO FILE SUPPLEMENTAL BRIEFING

On February 8, 2018, Plaintiff LaPorte, along with Adam and Ashley Kanuszewski, and Lynnette Wiegand, individually and as parent-guardians of their minor children, filed suit against the Michigan Department of Health and Human Services ("the Department" or "MDHHS"), Nick Lyon[1] (the then-Director of MDHHS), Dr. Sandip Shah (Director of the Bureau of Laboratories), Dr. Sarah Lyon-Callo (state epidemiologist), Mary Kleyn (Manager of the Newborn Screening Section), Michigan Neonatal Biobank, Inc., and Dr. Antonio Yancey (Director of the Michigan Neonatal Biobank). ECF No. 3. The Complaint alleged that Defendants violated Plaintiffs' Fourteenth Amendment (substantive due process) rights by extracting blood from infants and then storing those "blood spots" without adequate parental consent (Counts I and II). Plaintiffs further alleged that Defendants violated their Fourth Amendment rights by extracting and then testing the blood spots (Count III) and by indefinitely storing the blood spots (Count IV). ECF No. 26.

[1] Elizabeth Hertel is the current Director of the Department of Health and Human Services.

Defendants filed separate motions to dismiss. ECF Nos. 32, 33, 34. Those motions were eventually granted, and the Complaint was dismissed. ECF Nos. 50, 51.

On August 8, 2018, Plaintiffs appealed this Court's decision to the United States Court of Appeals for the Sixth Circuit. ECF No. 52. The Sixth Circuit affirmed in part and reversed in part, remanding two claims for further proceedings: first, the Plaintiff-parents' substantive due process claim for the storage of the blood samples seeking injunctive and declaratory relief (Count II); and second, the Plaintiff-children's Fourth Amendment claim for the storage of the blood samples seeking injunctive and declaratory relief (Count IV).

On April 4, 2020, the case was consolidated with *LaPorte v. Gordon*, case no. 20-10089 (E.D. Mich. 2020). ECF No. 104. However, the *LaPorte* Plaintiffs have since voluntarily dismissed their claims from case no. 20-10089. ECF Nos. 114, 116, 118, 120.

I.

A.

The State of Michigan created a newborn screening program in 1965. 1965 PA 119. The program initially only required health professionals to test newborn infants for phenylketonuria which "can cause intellectual disability, seizure, behavioral problems, and other mental disorders." ECF No. 147 at PageID.4196–97. The majority of the more than 50 disorders tested for today are identified through a blood test, although the program also includes a hearing and critical congenital heart defect screening that is not challenged in this lawsuit. ECF No. 147-24 at PageID.4365 (Lyon-Callo Dep.). MDHHS Defendants concisely explain the history of the screening law,

> [B]y 1978 the statute was amended to allow additional diseases to be tested and to provide that a person who violates the statute's newborn screening requirements is guilty of a misdemeanor.
>
> To ensure the quality, consistency, and efficiency of newborn screening through centralized screening, the statute was amended in 1987 to permit the Michigan

> Department of Health and Human Services ('MDHHS') to require that newborn screening be performed at the MDHHS Laboratory. In 2000, the statute was again amended to, among other things, expressly exempt newborn screening testing from informed consent requirements and require MDHHS to: (1) develop a schedule for the retention and disposal of residual dried blood spots ('DBS') after newborn screening is completed; (2) make the DBS available for medical research during the established retention period; and (3) publish a pamphlet explaining the newborn screening program and statutory requirements, including the retention and disposal period for DBS and that they may be used for medical research.

ECF No. 147 at PageID.4197–98.

Currently, Michigan law requires all newborn infants to be tested for phenylketonuria, galactosemia, hypothyroidism, maple syrup urine disease, biotinidase deficiency, sickle cell anemia, congenital adrenal hyperplasia, medium-chain acyl-coenzyme A dehydrogenase deficiency, and "[o]ther treatable but otherwise disabling conditions as designated by the department." MCL § 333.5431(1). According to MDHHS, the State tests for over 50 disorders, and more than 250 babies born each year in Michigan are diagnosed with one of the rare disorders. ECF No. 147-2 at PageID.4243 (*Michigan Newborn Screening Questions and Answers*, MDHHS). The tested disorders "may affect blood cells, brain development, how the body breaks down nutrients from food, lungs and breathing, hormones, and how the body fights infection." ECF No. 147-3.

"Between 24 and 36 hours of life, a few drops of blood are drawn from a baby's heel to fill five or six spots on a filter paper card." ECF No. 135-4 at PageID.2071 (*1965-2015 Michigan Newborn Screening: A Public Health Success Story*, MDHHS); ECF No. 147-2 at PageID.4244 (*Michigan Newborn Screening Questions and Answers*, MDHHS). Michigan law provides that the newborn screening test is exempt from the State's informed consent requirements. MCL § 333.5431(2) ("The informed consent requirements [for genetic testing] do not apply to the tests required under subsection (1). The tests required under subsection (1) shall be administered and

reported within a time and under conditions prescribed by the department. The department may require that the tests be performed by the department."). Simply stated, parental consent is not needed for the screening. However, the Department is required to inform parents if the results of a test are positive. *Id.* § 333.5431(3). An individual who violates either the statute or rules promulgated by MDHHS for the screening program is guilty of a misdemeanor. *Id.* § 333.5431(5). After the infant's blood is tested, the remaining dried blood spots ("DBS") are sent to MDHHS.

The two remaining questions in this case concern MDHHS' storage and subsequent use of the DBS for research.

B.

There are multiple entities involved in the newborn screening program and later storage of the excess DBS[2]: MDHHS, the Michigan BioTrust, and the Michigan Neonatal BioBank ("MNB" or "BioBank"). The Michigan BioTrust is a state program operated by MDHHS "that addresses the residual dried blood spots." ECF No. 147-24 at PageID.4336 (Lyon-Callo Dep.). The BioTrust oversees the storage and research of the DBS. *Id.* at PageID.4343–49 (Lyon-Callo Dep.); *Newborn Screening Blood Spots*, MDHHS, https://www.michigan.gov/documents/mdch/Dried_Blood_Spot_Research_Table_Public_Report_347898_7.pdf [https://perma.cc/6NNN-38AR][3]. However, the State does not have the capacity to store all the excess DBS, so it contracts with the BioBank to store most of the excess DBS. ECF No. 147-24 at PageID.4344–46 (Lyon-Callo Dep.). Accordingly, the BioBank is the "depository" whose sole job is to "store the blood spots." ECF No. 147-31 at PageID.4680 (Yancey Dep.); ECF No. 135-35 at PageID.2372. Director Yancey also promotes the BioBank to researchers, including sharing pamphlets and other promotional material, including at Wayne State's new faculty

[2] The term "excess DBS" refers to DBS that were not used for the screening program test.
[3] The research summary report was cited in MDHHS Defendants' brief. ECF No. 147 at PageID.4201.

orientations. ECF No. 147-24 at PageID.4388 (Lyon-Callo Dep.); ECF No. 147-31 at PageID.4742–43 (Yancey Dep.).

Plaintiff-parents are the parents of the nine Plaintiff-children. Adam and Ashley Kanuszewski are parents of DWL[4] (born Jan. 17, 2018), RFK (born April 22, 2013), and CKK (born Feb. 10, 2016). Shannon LaPorte is mother to MTL (born October 19, 2008) and EMO (born Feb. 6, 2017). Lynette Wiegand is mother to LRW (born Nov. 21, 2011), CJW (born July 17, 2013), HJW (born December 24, 2014), and MLW (born Jan. 30, 2017). *See* ECF No. 26.

Defendants are employees of MDHHS or of the Michigan Neonatal BioBank. Defendant Mary Seeterlin is the Section Manager of the Newborn Screening Section at the MDHHS Laboratory. ECF No. 147-22 at PageID.4322. Mary Kleyn is the Manager of the Newborn Screening Follow-up Section at MDHHS. ECF No. 147-23 at PageID.4329. Elizabeth Hertel is the current Director of the Michigan Department of Health and Human Services. Doctor Sarah Lyon-Callo is director of the Bureau of Epidemiology and Population Health at MDHHS. ECF No. 147-24 at PageID.4340 (Lyon-Callo Dep.). Doctor Sandip Shah is the state public health laboratory director for MDHHS. ECF No. 135-42 at PageID.2428. He "oversee[s] all the public health-related testing in [the MDHHS] laboratory, state laboratory as well as county laboratories as a regional laboratory system." *Id.* at PageID.2438 (Shah Dep.). Drs. Shah and Lyon-Callo "are responsible for the dried blood spots in the Michigan BioTrust program that are at the Michigan Neonatal BioBank for storage and distribution at the direction of the Michigan Department of Health and Human Services." ECF No. 147-24 at PageID.4339 (Lyon-Callo Dep.). Dr. Antonio Yancey is an employee of Wayne State University and is the Director at the BioBank. He is

[4] Adam Kanuszewski is not the biological or adoptive father of DWL.

responsible for the finances of the BioBank and oversees its operations and assets. ECF No. 147-31 at PageID.4675 (Yancey Dep.).

C.

Six blood spots are collected from the infants for testing shortly after birth. Usually one blood spot is needed for the newborn testing program. If a test has an abnormal result, a second test is required. ECF No. 147-2 at PageID.4244 (*Michigan Newborn Screening Questions and Answers*, MDHHS). After testing is complete, one DBS is saved by MDHHS for future use by the child or parents. *Id.*; ECF No. 147-8 at PageID.4269. The DBS saved for future use has previously been used "to help diagnose a disease in [a] child or to find reasons for a child's untimely death." ECF No. 147-10; ECF No. 146 at PageID.4160–62.

The remainder of the DBS (usually four spots) have all identifying information removed, are given a code number, and then stored at the BioBank. ECF No. 147-2 at PageID.4244 (*Michigan Newborn Screening Questions and Answers*, MDHHS). Only MDHHS has the ability to re-identify the DBS. MDHHS regulations provide that DBS may be stored for up to 100 years. ECF No. 147-4 at PageID.4249 (MDHHS Administrative Regulations); ECF No. 147-12 at PageID.4284; ECF No. 135-22 at PageID.2226; ECF No. 135-32 at PageID.2369 (BioTrust FAQs). However, Mary Seeterlin averred in an affidavit that DBS, demographics, and BioTrust forms are retained for 35 years and the testing data is retained for 22 years. ECF No. 141-22 at PageID.3007. All DBS collected prior to July 1984 have been destroyed. ECF No. 147-11 at PageID.4282; ECF No. 147-12; ECF No. 135-32 at PageID.2369 (BioTrust FAQs).

The de-identified DBS are used for "[Newborn screening program] quality assurance, test improvement, and test development [which] helps to ensure accurate and timely screening for other babies." ECF No. 135-13 at PageID.2186; ECF No. 135-32 at PageID.2369 (BioTrust

FAQs). Other spots are used for crime victim identification and medical research. ECF No. 135-13 at PageID.2186; ECF No. 147-24 at PageID.4400 (Lyon-Callo Dep.).

Mary Seeterlin, the Section Manager of the Newborn Screening Section at the MDHHS Laboratory, states that storage of the DBS is essential to the newborn screening program. ECF No. 147-22 (Seeterlin Declaration). In order for the Michigan Newborn Screening Laboratory to retain certification from the Clinical Laboratory Improvements Amendments (which includes review by the FDA, CDC, and Center for Medicare and Medicaid) and the College of American Pathologists, "analytical validation" must occur "for each test, method, or instrument system before use in patient testing." *Id.* at PageID.4323. Residual DBS are used to perform these analytical validation tests. *Id.* In addition, the screened disorders are rare and replacement of these rare DBS samples for use in validation testing "is not possible." *Id.* at PageID.4324 (Seeterlin Declaration). Further, "retesting [of the DBS] is valuable for root cause analysis of [a] false negative event[5] and allow for elucidation of causation between preanalytical, analytical, or post analytical origin." *Id.*

The DBS are also used for research. According to Dr. Lyon-Callo, the DBS form "an important resource . . . for researchers to be able to develop new tests that would enable the detection of severe disorders of the newborn period through the newborn screening process or other medical process at time of birth." ECF No. 147-24 at PageID.4391 (Lyon-Callo Dep.). DBS are also used for public health research. MDHHS regulations provide that DBS research may include (but is not limited to) "prenatal, childhood or adult-onset disorder [and] environmental exposures." ECF No. 147-8 at PageID.4266. The regulations prohibit research for "chemical, biological or nuclear warfare[,] cosmetics[, and] other non-health related ventures unless for purposes related to injury or medical conditions." *Id.* MDHHS provides that the research "aims to

[5] That is, when testing of the DBS failed to identify a rare disorder.

improve the health of communities." ECF No. 147-10. "Samples are 'double de-identified' before a researcher receives them." ECF No. 135-9 at PageID.2168.

Dr. Lyon-Callo states that the BioTrust for Health was created because

> there was recognition that there was this population-based set of residual sample that could be a very valuable resource for research into questions of public interest and questions for public good. . . . It's a very important resource for understanding exposures and conditions that babies were in during one of the most sensitive periods of development in terms of gestation.

ECF No. 147-24 at PageID.4390 (Lyon-Callo Dep.). Research on DBS "has been instrumental in developing [newborn screen program] tests for the debilitating disorders Spinal Muscular Atrophy and Niemann-Pick C Disease. Research facilitated by the BioTrust has also contributed to advancements in the study of cancers and environmental exposure." ECF No. 135-13 at PageID.2187.

Michigan law permits the DBS to be used for medical research "as long as the medical research is conducted in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks." MCL § 333.5431(7). The Department is required by law to provide a pamphlet explaining the testing program, the purpose of storing the DBS after testing, and the medical research conducted on the stored DBS. *Id.* § 333.5431(8). Researchers do not receive directly identifiable information, without specific informed consent from the parents.[6] ECF No. 147-8 at PageID.4268 (MDHHS regulations).

D.

i.

Consent is not obtained from the parents for the heel prick and the newborn screening tests. ECF No. 135-13 at PageID.2186. Neither is consent obtained from the parents for storing the DBS.

[6] The regulation does not specify how this specific informed consent is obtained.

ECF No. 141-13. Beginning in May 2010, however, express consent for use of the DBS for research is obtained from a parent at the time of birth. ECF No. 147-24 at PageID.4369–71 (Lyon-Callo Dep.). Even if the parent refuses consent for research, however, all excess DBS are stored "indefinitely." ECF No. 147-11 at PageID.4282. The research consent form directs parents to contact MDHHS if they do not want the DBS stored.

For DBS collected between July 1984 and May 2010, express consent for medical research was not obtained. ECF No. 135-42 at PageID.2430 (Shah Dep.) As a result, the MDHHS Institutional Review Board "waived" informed consent for samples collected prior to the introduction of express consent. ECF No. 147-14; ECF No. 147-24 at PageID.4350–51 (Lyon-Callo Dep.). The Institutional Review Board relied in part on 45 C.F.R. § 46.116,[7] which states that informed consent may be waived if

> (i) The research involves no more than minimal risk to the subjects; (ii) The research could not practicably be carried out without the requested waiver or alteration; (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

45 C.F.R. § 46.116(h). The regulation continues, "The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective." *Id.* § 46.116(i). Dr. Shah testified that there is "no harm done" with the research because

[7] "The HHS regulations for the protection of human subjects in research at 45CFR 46 [sic] . . . provide[] a robust set of protections for research subjects[,] provide additional protections for certain populations in research[, and] provide[] requirements for IRB registration." *45 CFR 46*, HHS, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html [https://perma.cc/4LTZ-JKLN] (last visited July 27, 2021).

it is conducted for "human good," that is, "for improvement of newborn screening programs or development of new tests, development of new equipment, maybe more advance [sic] and so on." ECF No. 135-42 at PageID.2431 (Shah Dep.).

DBS collected prior to May 2010 may be used for research unless the parent (or adult child) contacts MDHHS and requests that the DBS not be used. ECF No. 147-10; ECF No. 147-11. Authorized use of the DBS includes "newborn screening quality improvement and test development, approved research projects, parent-directed use, and crime-victim identification." ECF No. 147 at PageID.4201. The parent (or adult child) must contact MDHHS directly to request the DBS be destroyed or not be used for research. ECF No. 147-13. DBS from about four million people were collected before May 2010, including two Plaintiff-children. ECF No. 147-11 at PageID.4282. The informed consent waiver was approved based "on the understanding that some effort would be made to provide a general public notice that one can have their blood, or their child's blood, excluded from research use, e.g. a website posting, press release, etc." ECF No. 147-14 at PageID.4289. The informed consent waiver has been renewed annually since 2010. ECF No. 147-14.

Hospitals choose when to present the consent card to parents. ECF No. 135-42 at PageID.2434 (Shah Dep.). MDHHS does not audit all nursery employees to ensure they have been properly trained about the newborn screening program. However, if a significant number of consent forms are returned blank or the Department receives complaints regarding a specific hospital, the Department will reach out and conduct more training. ECF No. 147-24 at PageID.4363 (Lyon-Callo Dep.). In addition, the consent form itself references the MDHHS fact sheet with more information regarding the program. *Id.* at PageID.4358–59 (Lyon-Callo Dep.).

ii.

On April 22, 2013 Ashley Kanuszewski signed a statement explaining that she understood that participation in the Michigan BioTrust for Health research was voluntary for RFK. ECF No. 147-15. On February 10, 2016, she signed a consent form providing that CKK's blood spots may be used for health research. ECF No. 147-16. Her oldest child, DWL, was born prior to the express consent process.

On February 6, 2017 Shannon LaPorte declined to have her child's, EMO, DBS used for research. ECF No. 147-17. Her older child MTL was born prior to the express consent process.

On November 22, 2011 and July 18, 2013, Lynette Wiegand signed statements explaining that she understood participation in the Michigan BioTrust for Health research was voluntary for children LRW and CJW. ECF No. 147-18; ECF No. 147-19. On December 25, 2014, she signed a consent form allowing HJW's DBS to be used for health research. ECF No. 147-20. On January 20, 2017, Wiegand did not allow MLW's, her fourth child, excess blood spots to be used for research. ECF No. 147-21.

No parent provided express consent for storage of the DBS because none was or is sought. No parent sought to destroy their child's DBS. MDHHS checked its database and confirmed that none of Plaintiff samples "were used for quality assurance, research, or another purpose while stored at the MDHHS Laboratory after newborn screening testing was completed." ECF No. 147-22 at PageID.4326 (Seeterlin Declaration).

E.

The mission of the Michigan Neonatal BioTrust is stated in its "business plan" as follows:

> [T]o create and maintain a bank of valuable research materials from the dried blood spots (DBS) owned by the Michigan Department of Community Health, and to become the most comprehensive and useful bank for research into the origins

> prevention and cures for diseases of public health concern with emphasis on the public health concerns of Michigan's citizens.
>
> The overall vision behind the Michigan Neonatal BioTrust (MNB) is to establish a repository that will serve as a unique resource of materials and data for researchers. The potential for insight gained from studies utilizing newborn DBS will expand exponentially when the MNB facilitates linkages with other public health or clinical databases and registries, such as vital records, birth defects and cancer registries, or other disease surveillance systems, making the dried blood spots a unique and valuable resource for research. Marketing and revenue from user fees will generate cost recovery for MNB operations.
>
> The MNB will provide an advantage to academic and commercial research because they will have access to an organized, searchable sample collection with associated clinical data that is much larger than any single institute could provide. This will create opportunities for research in basic and translational medicine in Michigan and give academic researchers applying for outside funding a strong advantage. For example funding for research through the National Institute of Health's Whole Genome Association depends on the availability of and access to large numbers of samples. Both academic and commercial discoveries from the resulting research can provide the basis for economic development in Michigan.

ECF No. 135-7 at PageID.2094 (BioTrust Business Plan). The BioTrust's goals include "(1) mak[ing] blood spots more useful for medical and public health research while protecting privacy, (2) stor[ing] blood spots to better preserve the samples, (3) encourage[ing] research, (4) engag[ing] and inform[ing] the public and (5) allow[ing] personal decision-making." ECF No. 135-3 at PageID.2371 (BioTrust FAQs).

The BioTrust Scientific Advisory Board and the MDHHS Institutional Review Board must approve any research project and ensure the material transfer and data use agreements are completed. ECF No. 147-8 at PageID.4267 (MDHHS regulations).

The BioBank works exclusively with MDHHS and researchers, not the general public. ECF No. 147-31 at PageID.4690 (Yancey Dep.). The BioBank charges researchers for use of the blood spots but maintains that the DBS are not "sold." *Id.* at PageID.4720–21 (Yancey Dep.); ECF No. 135-13 at PageID.2187.

The BioBank is funded in part by a State of Michigan grant ($140,000 annually). It also charges researchers $10 "per punch," that is, per DBS, to cover its operation expenses. In addition, many students and staff are paid by Wayne State University. ECF No. 147-31 at PageID.4722–23. (Yancey Dep.).

The BioBank appears to be an innovative venture in terms of public health research. In one of its solicitation letters, the BioBank states,

> The BioBank is innovative because it makes available to public health researchers for the first time more than 27 years of well documented blood samples from a cohort of millions of Michigan newborns. Across the United States, only Michigan and California have successfully developed biobanks to make their dried blood spots available for public health and medical research. Most States retain their samples for five years or less, and only a few States have begun taking steps to develop banks for their own samples.

ECF No. 135-9 at PageID.2167.

The BioBank also promotes the research potential of DBS in its background materials, stating,

> [DBS] have already been used to investigate issues such as exposure to environmental pollutants, genetic factors associated with susceptibility to infection, and childhood cancer. Because more than 99% of Michigan infants are screened at birth, dried blood spots represent an entire birth cohort and would allow population-based studies that overcome shortcomings present in other research designs such as small sample size.
>
> The Biobank's samples have also been used for studies of spinal muscular atrophy, Sudden Unexplained Infant Death Syndrome, congenital heart defects, autism, cerebral palsy, and fetal alcohol syndrome – some of the most intractable childhood disorders in the nation – as well as to develop a newborn screening test for Severe Combined Immune Deficiency (SCID). The samples enable researchers to do studies that were not possible before to solve complex health issues using human rather than animal samples.
>
> The research value of the samples increases greatly when the Michigan Department of Community Health links them to information in the State's public health databases. The Department of Community Health functions as an Honest Broker to match the samples with their associated clinical data while removing identifying

> information about the donor. By matching the blood samples against the birth defects registry, the cancer registry, live births, death records or the disease surveillance system, for example, a researcher can study a newborn blood sample that is associated with a known health outcome.
>
> The Biobank offers a unique solution to the problems associated with locating, identifying, preparing, storing and mining high quality biological samples for research.

Id. at PageID.2167.

F.

MDHHS policy dictates that a parent (for a minor child) or an adult may request the blood spots be destroyed after providing a copy of their birth certificate and government-issued identification. ECF No. 147-4 at PageID.4249 (MDHHS regulations). The regulations provide that

> The department may release part, or all, of the residual DBS upon written request of the individual for research studies or other uses. MDHHS may release part, or all, of the de-identified specimen for NBS quality assurance and test development or public health or medical research with appropriate approval of the departments scientific advisory panel and Institutional Review Board. MDHHS will reserve part of the specimen solely for the use of the individual or parent/guardian, unless requested otherwise by an authorized individual.

Id. at PageID.4249 (MDHHS regulations).

MDHHS' Residual Newborn Screening Blood Spot Directive provides that an individual may request (1) all remaining blood spots be destroyed (including the DBS stored by MDHHS), (2) that only those blood spots stored for research be destroyed, or (3) that MDHHS only store the blood spots but not use them for research. ECF No. 147-5.

Between 2009 and 2020, MDHHS destroyed blood spots in response to 437 directives, an average of 36 per year. ECF No. 147-23 (Kleyn Declaration). Plaintiffs have not submitted a directive to have the blood spots from their children destroyed. *Id.* Even if the DBS are destroyed upon request, MDHHS "retain[s] the information on the child and what their newborn screening result was." ECF No. 147-24 at PageID.4396 (Lyon-Callo Dep.).

When a request to destroy a sample is given to the State, the BioBank does not destroy the sample. ECF No. 147-31 at PageID.4716–17 (Yancey Dep.). The BioBank locates the sample and then transmits it to the State so that it can be destroyed. *Id.*

II.

A motion for summary judgment should be granted if the "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). The moving party has the initial burden of identifying where to look in the record for evidence "which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the opposing party who must set out specific facts showing "a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (citation omitted). The Court must view the evidence and draw all reasonable inferences in favor of the non-movant and determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* at 251–52.

III.

A.

Defendant Yancey contends that because an alternate remedy exists—that Plaintiffs can request the destruction of the DBS—the constitutional questions need not be addressed. ECF No. 149-1 at PageID.4877; ECF No. 145 at PageID.3894. Yancey argues that the doctrine of constitutional avoidance "encourages courts to avoid making a pronouncement concerning the federal constitution when a state law ground is available to decide a case." ECF No. 149-1 at PageID.4892. State Defendants also make an unusual standing argument in their reply brief stating that "Plaintiffs must prove an injury before the burden shifts to the defendants and Plaintiffs have

failed to make that showing." ECF No. 162 at PageID.5519. In response, Defendants argue that "[f]raming this choice as an exhaustion of remedies requirement is a strawman of Plaintiffs' creation—the ability to request destruction or return of Plaintiffs' DBS does not preclude them from filing suit, but rather is evidence that Plaintiffs' have at all times had the ability to control the retention and authorized uses of their DBS." *Id.* at PageID.5520.

The Sixth Circuit addressed and dismissed both arguments on appeal. First, the court held that there is no exhaustion requirement for § 1983 claims. *Kanuszewski*, 927 F.3d at 409 n.5 ("Defendants cite no cases explaining what the significance of alternate remedies being available has in standing analysis, and Plaintiffs correctly point out that this argument suggests there is an exhaustion-of-remedies requirement to § 1983 claims, which Supreme Court precedent has expressly rejected."); *see also Monroe v. Pape*, 365 U.S. 167, 183 (1961) ("The federal remedy [under § 1983] is supplementary to [any] state remed[ies], and the latter need not be first sought and refused before the federal one is invoked.")).

Second, the circuit held that "there is a substantial risk that additional chemical analysis of the [DBS] will occur, meaning that this [ ] theory of injury affords the children standing to seek injunctive and declaratory relief . . . . [I]t is not too speculative to assert that the state or third parties may conduct chemical analysis on the blood samples—indeed, Plaintiffs allege that this is the very reason why the state retains the samples and why third parties obtain them." *Id.* at 410–11. Plaintiffs have the burden to demonstrate standing. *Kanuszewski v. MDHHS*, 927 F.3d 396, 405 (6th Cir. 2019). In the course of discovery, Plaintiff-children have demonstrated that the State allows third parties to conduct research on anonymized DBS. *See* Section I.E., *supra*. Defendants correctly contend that there are strong privacy protections for the samples (double anonymity and the ability for parents to request the DBS be destroyed). ECF No. 147-2 at PageID.4244; ECF No.

147-13. However, as discussed below, not all parents (on their children's behalf) consented to the ongoing storage or research of the DBS. The parents (on their children's behalf) cannot opt out of the program if they do not know their children's DBS are stored. There is a sufficient injury-in-fact for Plaintiff-children's seizure injury. As for the parents, the Sixth Circuit held that

> assum[ing] that Plaintiffs will be able to prove that the transfer and storage of their children's blood samples violates the parents' substantive due process rights . . . . parents have standing when the state interferes with their right to control the upbringing of their children. . . . Just as it represents a harm to parents when the state denies them their right to direct the education and religious upbringing of their children, it represents a harm when the state denies parents the right to direct the medical care of their children.

Kanuszewski, 927 F.3d at 411–12. As explained *infra*, the parents' fundamental rights to direct the medical care of their children was infringed upon by the state, and thus, the parents have standing.

B.

The first issue is whether Defendants infringed on Plaintiff-parents' substantive due process right to direct medical care for their children. The Sixth Circuit explained,

> On remand, Defendants will be free to produce evidence demonstrating that the parents consented to some or all of Defendants' actions vis-à-vis the children's blood samples. To the extent that the parents provided informed consent to Defendants' actions, no fundamental liberty interest would have been impinged because the parents would not have been denied the right to control their children's medical care, although it may be that merely "present[ing] [parents] with an option to opt out of having their child's blood used for research" as the district court seemed to believe occurred here is not sufficient if the default is for the state to use the samples for research. We note that consent to allow the state to conduct research on the children's blood samples does not necessarily imply consent to allow the state to sell the blood samples to third parties. Many questions about the nature and scope of parental consent remain, and the case should proceed to discovery so that the parties may produce evidence relating to these questions. On remand, the parties will also be able to produce evidence relating to whether Defendants had a compelling interest in retaining, transferring, and storing the children's blood samples after screening them for diseases, and whether Defendants' means for achieving their interest were narrowly tailored. Based on Plaintiffs' allegations, it seems unlikely that Defendants will be able to demonstrate a compelling interest, as the health of the child is no longer at stake after the samples have been tested for life-threatening diseases. Plaintiffs allege that Defendants conduct research on

> children's stored blood samples and seek to derive profit from the children's samples by selling them to third parties. On remand, Defendants may deny that they have a present or future commercial interesting in the blood sports (which, up to this point in the litigation, they have not done) and may present evidence demonstrating other purposes for retaining, transferring, and storing the samples.
>
> …
>
> The parents have a fundamental right to direct the medical care of their children, and their claims may go forward so that the parties can present evidence related to Defendants' actions and the legal implications of those actions. Specifically, the questions on remand will be whether the evidence demonstrates that Defendants' actions interfered with the parents' right to direct their children's medical care; and, to the extent they did interfere with the parents' fundamental rights, whether those actions survive strict scrutiny.

Kanuszewski, 927 F.3d at 420–21. (internal citation omitted).

As stated by the Sixth Circuit, the first question that must be confronted is "whether the evidence demonstrates that Defendants' actions interfered with the parents' right to direct their children's medical care." *Id.* The circuit clearly held that "[p]arents possess a fundamental right to make decisions concerning the medical care of their children." *Id.* at 418–19. When considering Defendants' 12(b)(6) motion, the circuit previously found that allegations that "Defendants retain the samples, transfer the samples to the Neonatal Biobank, and store the samples indefinitely for further use by the state or third parties. . . without informed parental consent . . . constitute[d] a denial of the parents' fundament right to direct the medical care of their children, and their actions must survive strict scrutiny." *Id.* at 420 (footnote omitted). Upon completion of discovery and Rule 56 briefing by the parties, it is clear that Defendants do in fact retain the DBS, transfer the samples to the BioBank, and indefinitely store the samples for use by the state and third party research. *See* Section I., *supra*. As such, Plaintiffs have not only alleged, but proven, that absent the parents' consent for research (discussed *infra*), Defendants interfered with Plaintiff-parents' fundamental right to direct the medical care of their children, as defined by the Sixth Circuit.

Both Yancey and the State Defendants emphasize Plaintiff-parents' testimony that the state's retention of their children's blood spots did not interfere with their right to direct the medical care of their children. ECF No. 147-25 at PageID.4438–39 (Adam Kanuszewski Dep.); ECF No. 147-26 at PageID.4469 (Ashley Kanuszewski Dep.); ECF No. 147-28 at PageID.4561 (Wiegand Dep.). However, a determination on the violation of a parents' fundamental right to direct the medical care of their children is a legal determination, which is not an appropriate inquiry for a lay person. *See Wolverine World Wide, Inc. v. American Insurance Co.*, 2020 WL 8340140 at * 4 (W.D. Mich. Feb. 28, 2020) ("A lay witness cannot testify as to legal conclusions . . . . Indeed, if testimony addresses issues with a separate, distinct and specialized meaning in the law different from that present in the vernacular, it calls for an impermissible legal conclusion.") (internal quotations and citations omitted) (collecting cases). Plaintiffs' counsel did not object to the question at the depositions, but this Court will not rely upon laypersons' legal conclusions to decide a motion for summary judgment, especially when Plaintiff-parents may have been unaware that they were reaching such a conclusion. Only Plaintiff Adam Kanuszewski is an attorney and the specific question he answered was, "Have you ever felt that your ability to determine the medical care for your child has been impacted by the taking of the dried blood spot card?" ECF No. 147-25 at PageID.4438–39. Such a question is distinct from whether his fundamental right to direct the medical care of his children was infringed upon.

The next issue is whether Plaintiff-parents consented to the research and/or storage of the DBS. If Plaintiff-parents consented, then there is no violation of a fundamental liberty interest. *Kanuszewski*, 927 F.3d at 420. The question of consent must be analyzed separately for the research and storage of the DBS.

i.

Starting in May 2010, Defendants began obtaining express consent for the use of excess DBS in research. ECF No. 147-24 at PageID.4351–54 (Lyon-Callo Dep.). The consent form has changed over the years (ECF Nos. 141-15, -16, -17, -18, -19, -20, -21), but it is clear that Plaintiffs Kanuszewski and Wiegand authorized MDHHS to use some of their children's DBS for research. *Compare* ECF No. 141-15 (Ashley Kanuszewski authorized for RFK), ECF No. 141-16 (Ashley Kanuszewski authorized for CKK), ECF No. 141-18 (Lynette Wiegand authorized for LRW), ECF No. 141-19 (Lynette Wiegand authorized for CJW), ECF No. 141-20 (Lynette Wiegand authorized for HJW), *with* ECF No. 141-21 (Lynette Wiegand declined research authorization for MLW), ECF No. 141-17 (Shannon LaPorte declined research authorization for EMO).

Without legal citation, Plaintiff-parents argue that their consent was not voluntary because it was obtained less than 24 hours after Plaintiff-mothers had given birth. ECF No. 135 at PageID.1944–45. However, Defendants explain that about 13% of mothers receive inadequate prenatal care and it is impractical to collect consent forms from countless prenatal care offices as opposed to the 80 birthing hospitals in Michigan. ECF No. 142 at PageID.3354–59. Second, Plaintiffs provide no evidence that non-party hospital workers or Defendant MDHHS employees coerced Plaintiff-mothers into providing their consent. Plaintiff-parents argue,

> There was no disclosure of what constitutes "medical research" or "health research." There is no mention that the samples are sold for monies. There is no mention that for-profit companies have access. There is no mention of how samples can be selected based on data like zip code, age, gender, or more, which when combined with other data, can reveal the identity of the person from their sample.

ECF No. 135 at PageID.1943. While it is true that the terms medical research and health research are not defined on the consent form, the consent forms signed by Plaintiff-parents indicate that they should have been provided with a pamphlet with a more complete description of the terms

used. *See e.g.*, ECF No. 141-15 ("You should have been given the booklet, '*After Newborn Screening*'. If not, please ask for it. This booklet describes the Michigan BioTrust for Health and how dried blood spots (DBS) could be used for medical research after newborn screening is complete. Please read this booklet and if you have any additional questions, you may call the Newborn Screening Program . . ."); ECF No. 141-16 ("The brochure, *Your Baby's Blood Spots*, gives details to help you make a choice about allowing your baby's blood spots to be used in health research. Please read this brochure. If you still have questions, please call the Department of Community Health . . ."); ECF No. 141-17 ("Before you sign this form please read, *Your Baby's Blood Spots*. It explains in more detail how your baby's blood spots may be used in health research through the Michigan BioTrust for Health. If you still have questions, please call the Michigan Department of Health and Human Services . . ."). Plaintiffs were not required to sign the consent form, and even if the hospital employee did not adequately explain the process, the form instructs new parents to ask for a pamphlet before signing the form. However, Plaintiffs still chose to sign the form.

Therefore, Plaintiff-parents' due process claims based on DBS research are precluded as to Kanuszewski children RFK and CKK and Wiegand children LRW, CJW, and HJW because consent for DBS research was obtained. Further, Plaintiff-parents' research claims are precluded as to LaPorte child EMO and Wiegand child MLW because the parents declined authorization for research and have presented no evidence that any research was conducted with the DBS extracted from EMO or MLW. ECF No. 147-22 at PageID.4326 (Seeterlin Declaration).

For Plaintiff-children DWL (Ashley Kanuszewski's child) and MTL (LaPorte's child), express consent was not obtained from the parents. Instead, the Institutional Review Board ("IRB") in 2010 voted to furnish its consent on behalf of the parents. ECF No. 147-14; ECF No. 147-24 at

PageID.4351–52 (Lyon-Callo Dep.). Defendants contend this is sufficient because it "is consistent with federal law." ECF No. 147 at PageID.4214. Federal regulation provides,

> An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
>
> (1) The research involves no more than minimal risk to the subjects;
> (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
> (3) the research could not practicably be carried out without the waiver or alteration; and
> (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

45 C.F.R. § 46.116(d). Defendants explain,

> The then-Michigan Department of Community Health Institutional Review Board (IRB) approved a procedure waiving informed consent for DBS obtained pre-2010 because (1) the research involves no more than minimal risk—risk is minimized by using already-held specimens, a widely accepted strategy that is not controversial; (2) the waiver does not adversely affect the rights and welfare of the individual because it does not require active participation and is anonymous; (3) the research could not practicably done [sic] without the waiver; and (4) individuals are provided with additional pertinent information when appropriate. Research done with this kind of waiver is commonplace nationally, and a finding invalidating waivers such as this could devastate legally and ethically sound research being done throughout the country, most of it unrelated to newborn screening.

ECF No. 147 at PageID.4215–16. Besides the reference to the foregoing regulation, Defendants provide no authority that an informed consent waiver from an IRB is sufficient to waive the constitutional requirement of informed parental consent. While this Court appreciates that MDHHS believes it followed federal law and sound medical ethics when it approved the waiver of informed consent, the question here, as framed by the Sixth Circuit, is whether the consent is valid to waive a parents' fundamental right to direct the medical care of their children.[8] If so, then there is no constitutional violation. If not, then strict scrutiny must be applied.

[8] This lawsuit is not a class action and only pertains to a parents' fundamental right to direct the medical care for their children, not an adults' right to direct their own medical care. While Defendants claim that

Defendants contend that Plaintiff Ashley Kanuszewski would have been

> on notice that DBS are retained and made available for research since at least April 22, 2013, when she signed an authorization allowing R.F.K.'s DBS to be available for research. Similarly, even if Plaintiff LaPorte was not informed by her healthcare professional at the time of M.T.L.'s birth—and the pamphlet in use at the time also noted DBS are retained—she has been on notice that DBS are retained and made available for research since at least February 6, 2017, when she signed a directive indicating that E.M.O.'s blood spots may not be used for health research.

Id. at PageID.4213–14. First, it is disingenuous to assert that because DBS from a younger child are stored and used for research that a parent would be on notice that the same testing, storage, and research occurred for an older child. Even if it were valid notice, the fact that parents may have learned about the process at a later date does not negate the initial lack of consent provided for research and/or storage of the DBS. In fact, because no consent is required prior to the newborn screening test, if neither child was flagged for a rare disease, the parents may not have even been aware that the older child had her blood tested, let alone that her DBS was being stored by the State.

Furthermore, even assuming that the consent procedure in 45 C.F.R. § 46.116(d) is sufficient for the purposes of due process—an issue which this Court does not decide—MDHHS has not shown that it followed the four requirements to ensure consent was received. While the DBS research involves minimal risk to the individuals whose samples are used—that is, the subject children—the waiver of informed consent will adversely affect their rights because their blood is being used for research without their consent or consent offered by their parents. 45 C.F.R. §§ 46.116(d)(1)–(2). In fact, the parents may not even know the State has excess DBS cards to be used for research. Pamphlets about the newborn screening program may have been at the hospital,

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any determination about insufficiencies in the informed consent process will have implications far beyond this lawsuit, this decision only affects named Plaintiffs and is focused on the violation of a fundamental right subject to strict scrutiny, as found by the Sixth Circuit.

but there is no record of whether Plaintiffs Kanuszewski and LaPorte were aware of the program and therefore could object to the storage or research. Third, the research can be practicably carried out without the waiver. *Id.* § 46.116(d)(3). In fact, the research could be limited to those whose parents signed the consent waiver since May 2010—currently more than 11 years of data. MDHHS records indicate that 86.5% of parents complete the consent form, and of those who complete the form, 73.9% consent to the use of DBS for research. ECF No. 142 at PageID.3358; ECF No. 141-24 at PageID.3014–15. Therefore, accounting for parents who did not complete the form or declined consent, 63.9% of parents consented to research. ECF No. 142 at PageID.3358; ECF No. 141-24 at PageID.3014–15. Defendants argue they require at least 5,000 samples to check the over 29 testing instruments each year. ECF No. 147-22 at PageID.4323–24; ECF No. 147 at PageID.4219–20. A simple calculation of 29 instruments multiplied by 5,000 samples equals 145,000 individual DBS required for testing each year. MDHHS currently has 11 years' worth of samples, and an estimated 70,000[9] new research eligible DBS cards become available each year. Most DBS excess cards have five blood spots remaining; one of which is kept by MDHHS. Therefore, there are usually four blood spots eligible for research. Multiplying the 70,000 DBS cards eligible for research by four blood spots results in 280,000 new blood spots eligible for research per year, more than double the minimum required for instrument testing. This still leaves the other half of the DBS eligible for general public health research. Defendants have not demonstrated that they need the samples collected prior to May 2010 for research or instrument testing.

[9] Assuming an average of 110,000 children born annually in Michigan, multiplied by the 63.9% parental consent rate. *Live Births and Crude Birth Rates*, MDHHS, https://www.mdch.state.mi.us/osr/natality/tab1.1.asp [https://perma.cc/4HNH-FUMG] (last visited 6/30/2021).

Finally, despite the IRB waiver indicating that sufficient information would be publicly provided for parents to request the destruction of DBS if they so choose, the parents all testified that they did not know about the destruction process prior to this lawsuit. *See* ECF No. 141-14 at PageID.2970 ("Please note we based satisfaction for criterion (4) on the understanding that some effort would be made to provide a general public notice that one can have their blood, or their child's blood, excluded from research use, e.g. a website posting, press release, etc. Please provide information on how that will be done when plans are finalized.") (MDHHS Institutional Review Board Approval Form); ECF No. 147-25 at PageID.4426 (Adam Kanuszewski Dep.); ECF No. 147-26 at PageID.4459 (Ashley Kanuszewski Dep.); ECF No. 147-27 at PageID.4520 (LaPorte Dep.); ECF No. 147-28 at PageID.4541–44 (Wiegand Dep.). Defendants have not demonstrated that the waiver of informed consent by the IRB was constitutionally sufficient to conduct research on the children's DBS.

ii.

While some Plaintiff-parents consented to research on the DBS, Defendants did not seek express consent to store the DBS. Recent versions of the research consent form indicate that DBS will be stored for up to 100 years and provide that parents may seek destruction of the DBS by contacting MDHHS. ECF No. 147-4 at PageID.4249 (MDHHS Administrative Regulations); ECF No. 147-13. The Sixth Circuit concluded that the ability to opt out of research is not the same as consent thereto. *Kanuszewski*, 927 F.3d at 420. It also noted that consent for research does not extend to consent to sell blood samples. *Id.*

Consent to research does extend to consent to store the DBS because by giving consent to conduct research on the DBS, one inherently gives consent to store DBS for said research. However, no consent was given for MDHHS to store the additional blood spot that is kept for

parental use. Therefore, Plaintiff-parents have due process claims for the storage of their children's DBS. Plaintiff-parents Adam and Ashley Kanuszewski and Plaintiff-parent Wiegand have storage claims only for the DBS extracted from RFK and CKK (Kanuszewski) and LRW, CJW, and HJW (Wiegand) and stored for parental use, while Plaintiff-parents of DWL, MTL, EMO, and MLW have claims for all stored DBS because they did not authorize MDHHS to use their children's DBS for research.

iii.

In summary, the parents of RFK and CKK (Adam and Ashley Kanuszewski) and LRW, CJW, and HJW (Lynette Wiegand) expressly consented to research on, and implicitly consented to the storage of, the research-eligible samples. The parents' Fourteenth Amendment claims for research will be dismissed. Similarly, Plaintiff-parents of EMO (LaPorte) and MLW (Wiegand) do not have a due process claim premised on research because they denied consent for research and there is no evidence that their children's DBS were used for research. Their Fourteenth Amendment claims for research will be dismissed. However, the Fourteenth Amendment research claims of Plaintiffs Ashley Kanuszewski (for DWL) and Shannon LaPorte (for MTL) require a strict scrutiny analysis because consent for research was not obtained.

Because no consent was obtained for the ongoing storage of the one DBS extracted from each child and stored by MDHHS[10] for parental use, all Plaintiff-parents' Fourteenth Amendment storage claims survive and, according to the Sixth Circuit, invoke strict scrutiny.

[10] Plaintiff-parents of EMO (LaPorte's child) and MLW (Wiegand's child) declined consent to conduct research on the DBS. As such, their claims for a Fourteenth Amendment storage claim applies to the DBS stored at MDHHS and the DBS stored at the BioBank. Plaintiff Ashley Kanuszewski (on behalf of DWL) and Shannon LaPorte (on behalf of MTL)'s Fourteenth Amendment storage claims also apply to the DBS stored at MDHHS and the remainder of the samples stored at the BioBank because consent was never sought, nor obtained, for research.

C.

i.

The Sixth Circuit held that parents have a fundamental right to direct their children's medical decisions. *Kanuszewski*, 927 F.3d at 418–19. But that right is not without limit. The Supreme Court has held that states have a compelling interest in "safeguarding the physical and psychological well-being of a minor." *Globe Newspaper Co. v. Superior Court for Norfolk County*, 457 U.S. 596, 607–08 (1982). And where that compelling interest collides with the rights of a parent, the state's interest may prevail. For example, the Tenth Circuit, which recognizes that "precedent reasonably suggests that the Due Process Clause provides some level of protection for parents' decisions regarding their children's medical care," *PJ ex rel. Jensen v. Wagner*, 603 F.3d 1182, 1197 (10th Cir. 2010), previously found that two parents "did not have a clearly established constitutional right to refuse" chemotherapy for their son who had been diagnosed with life-threatening cancer, *id.* at 1198.

State Defendants argue that "all residual DBS may be used by MDHHS for limited purposes necessary to maintain the ongoing function of the newborn screening system. Retention may benefit the individual from whom the DBS were obtained . . . but of greater importance is the value to the public health in maintaining and expanding the newborn screening program, allowing for the identification and treatment of congenital disorders in all newborns." ECF No. 147 at PageID.4219. The Association of Public Health Laboratories' ("APHL") amicus curiae brief explains the necessity of storing and conducting research on excess DBS, specifically for "(1) laboratory quality control, quality assurance and improvement; (2) calibration of equipment; (3) evaluation of equipment, reagents, and methods of newborn screening tests for conditions approved for screening by the program; (4) validation of equipment and screening methods; (5)

development, testing, and maintenance of a plan to ensure continuity of operations in the event of an emergency; (6) assuring competency of testing personnel." ECF No. 146 at PageID.4154. Plaintiffs contend that "[b]ecause biobanking exceeds any possible needed use for genetic disease flagging purposes, Defendants do not have a compelling governmental interest in the retention and storage of blood spots for future unspecified uses by commercial or academic researchers." ECF No. 135 at PageID.1940.

To the extent that State Defendants conduct research (or authorize others to conduct research) on DBS to expand and strengthen the newborn screening program, such research advances a compelling interest. The continuation of the newborn testing program ensures that children born with life-threatening diseases or disorders are identified and that their parents are provided with the necessary information to protect their children. It is also narrowly tailored as such research focuses exclusively on improving accuracy with test results or discovering new ways to identify life-threatening conditions. Dr. Shah testified that about two tests are added each year. ECF No. 145-7 at PageID.4064.

To the extent that State Defendants conduct or allow general public health research to be conducted on excess DBS without consent, such research does not advance a compelling interest. While "the state has a wide range of power for limiting parental freedom and authority in things affecting the child's welfare . . . includ[ing], to some extent, matters of conscience and religious conviction," *Prince v. Massachusetts*, 321 U.S. 158, 166–67 (1944), that power does not encompass public health research, unrelated to the newborn testing program, on excess DBS after the samples have been tested for life-threatening diseases.

Nevertheless, State Defendants overemphasize the use of the research for the newborn testing program in their briefing. The business plan for the BioTrust provides that the goal of the

BioBank is "to become the most comprehensive and useful bank for research into the origins, prevention and cures for diseases of public health concern with emphasis on the public health concerns of Michigan's citizens." *See* ECF No. 135-7 at PageID.2094. APHL's amicus brief outlines the "unique" resource that DBS provide. ECF No. 146 at PageID.4156–60. It explains that "[r]esidual DBS specimens can be used for case studies of rare diseases, cross-sectional studies of the prevalence of a particular condition or exposure, case-control studies, and birth cohort studies. Medical and public health research using residual DBS specimens have included: (1) studying the incidence of different gene variants for an inherited conditions (hereditary hemochromatosis); (2) developing additional laboratory screening methods (sickle cell diseases); and (3) searching for new disease markers (childhood leukemia)." *Id.* at PageID.4158 (internal quote and citation omitted). The research conducted by the BioBank is not used solely to expand the newborn testing program, but for other public health research. Enhancing public health research is a laudable goal and one that hopefully has success with DBS obtained from parents who have given consent. To the extent that research is conducted for public health purposes not directly connected to the care of the newborn children, the practice fails to advance a compelling governmental interest.

Further, the public health research is not narrowly tailored. MDHHS Defendants argue that DBS research is anonymous and may only be used for approved medical research. ECF No. 147 at PageID.4223–24. Approved purposes for the DBS include, "newborn screening quality improvement and test development, approved research projects, parent-directed use, and crime-victim identification." *Id.* State Defendants explain that DBS research is anonymized, both by MDHHS when it provides the DBS to the BioBank and again when the BioBank gives the samples to the researchers. *Id.*

The privacy protections for the research, while important, do not address the relevant question. Defendants themselves list the newborn program testing separate from research projects—a further indication that the public health research projects are not a necessary part of newborn screening program test development. Again, while such public health research may have significant benefits, and this Court is satisfied that it does, it is not narrowly tailored to the protection of the newborn infants.

Plaintiff-parents have demonstrated that there is no genuine issue of material fact that the State infringed upon their fundamental right to direct the medical care of their children and did so without advancing a compelling governmental interest by narrowly tailored means. Even though Plaintiff-children's DBS have not been used for research yet, the potential for their use continues to exist. Defendants' Motions will be denied and Plaintiffs' Motion will be granted as to Plaintiff-parents' DBS research claims involving Plaintiff-parents of DWL and MTL. Conversely, as to all other claims premised on DBS research, because of the consent provided by Plaintiff-parents and lack of evidence of improper use of DBS, Plaintiffs' Motion for Summary Judgment will be denied and Defendants' Motion for Summary Judgment will be granted.

ii.

The next issue is the constitutionality of the ongoing storage of Plaintiff-children's DBS. State Defendants argue that the compelling interest for the storage of the DBS is the "benefit [to] the individual from whom the DBS were obtained (e.g., DBS are sometimes used by physicians in diagnosing and treating other conditions)" as well as to "public health in maintaining and expanding the newborn screening program, allowing for the identification and treatment of congenital disorders in all newborns." ECF No. 147 at PageID.4219–20 (citations omitted). They contend that

> Retained DBS are vital to maintaining an accurate and timely newborn screening program. . . . [T]he newborn screening laboratory utilizes over 29 instruments over nine different testing areas to screen DBS. The performance of each of these instruments must be verified prior to clinical use, which typically requires a minimum of 5,000 DBS, but can require more depending on the circumstances. There are similar requirements for validating instruments' results and improving the accuracy of laboratory equipment. The newborn screening laboratory transitions to new testing equipment virtually every year.

Id. (citations omitted). State Defendants further explain,

> Retaining DBS is vital for determining the cutoffs used in screening. Further, because some of the maladies screened for are quite rare, the pool of retained DBS must be very large; some disorders appear only once in ten years, yet the machinery must be maintained to ensure that when such a child is born, they are not missed. Retained DBS are also used for retesting to reduce the number of false negative results. Because of the dire health outcomes that can result from false negative tests, the newborn screening program takes this responsibility very seriously. Without retention of DBS, the newborn screening system could not function.

Id. at PageID.4220–21 (citations omitted).

Plaintiffs respond that there is no compelling interest in the storage of the DBS "as the health of the tested infant is no longer at stake after his or her samples have been fully vetted for life-threatening diseases." ECF No. 135 at PageID.1939 (emphasis omitted). They contend that "[b]iobanking practices that result [in] the non-consensual retention, storage, and use of bodily material personal and deeply-private medical and genetic information/data fails to be a sufficient interest." *Id.* at PageID.1941.[11]

The Sixth Circuit previously indicated "[i]t may well be that the [newborn screening program] would survive strict scrutiny to the extent that it involves drawing the children's blood and screening for life-threatening diseases." *Kanuszewski*, 927 F.3d at 420. State Defendants

[11] It should be noted that Plaintiffs also argue that the DBS are not only used for research but are sold to third parties for profit. ECF No. 160 at PageID.5226. Defendants clearly demonstrate that fees are charged to researchers for the use of the DBS to assist BioTrust to be financially independent, but the DBS are not sold "for profit." *See* ECF No. 142 at PageID.3366; ECF No. 141-29 at PageID.3280; ECF No. 141-30 at PageID.3327; ECF No. 135-7 at PageID.2094, 2107; ECF No. 135-9 at PageID.2168.

assert, and provide evidence, that storing the DBS and calibrating the testing instruments is a necessary part of the newborn screening program. ECF No. 135-13 at PageID.2186 (BioTrust for Health FAQs) ("As part of the NBS process, some of the residual dried blood spots are used by the MDHHS Laboratory for NBS quality assurance, test improvement, and test development. This helps to ensure accurate and timely screening for other babies."); ECF No. 135-32 at PageID.2369 (BioTrust FAQs); ECF No. 147-22 at PageID.4323 (Seeterlin Declaration) (Certification requires "analytical validation/verification of method performance specifications that laboratories must perform for each test, method, or instrument system before use in patient testing. Many of these testing requirements involve the use of residual DBS."). If all DBS were destroyed after the initial test, the newborn screening program itself would be severely compromised. However, not all DBS are used for calibration or are retested to avoid false positive or negative results. *See* ECF No. 135-13 at PageID.2186 (BioTrust for Health FAQs) ("[D]ried blood spots can also be used for de-identified medical research and crime victim identification.").

The second criteria of the strict scrutiny test is whether the challenged action is narrowly tailored to the compelling governmental interest. State Defendants argue it is. The DBS are stored in secure facilities unless they are destroyed or returned upon the request of a parent. ECF No. 147 at PageID.4222. Defendants further explain that they cannot use adult blood samples for the testing requirements. *See* ECF No. 162-1 at PageID.5529 (Seeterlin Declaration) ("Adult blood samples are different from newborn blood samples and may not reflect the population of Michigan."); ECF No. 146 at PageID.4156 ("In fact, several biochemical analytes utilized for the purpose of NBS are not present in infants, children, or adults. Because of this, residual DBS from newborns are the most appropriate source of quality control materials for NBS programs.").

Plaintiffs contend that the storage program is "substantially broader than necessary to achieve the government's interest of screening infants for newborn metabolic abnormalities to flag potential diseases." ECF No. 135 at PageID.1942. Stated another way, "the State Defendants fail to show that keeping everyone's blood samples since 1984 is necessary for basic machine calibration." ECF No. 160 at PageID.5226 (emphasis omitted). Plaintiffs continue, "All medical screenings could be fully and completely accomplished without the biobanking or post-screening uses and without any reduction of effectiveness of disease detection for newborn screening." ECF No. 135 at PageID.1942. Plaintiffs also argue that "[k]eeping residual blood samples for the State Laboratory's machine calibration certainly does not require that Plaintiffs' spots be sold or transferred to the Biobank or third-party researchers." ECF No. 160 at PageID.5226 (emphasis omitted).

Plaintiffs are correct, to a point. State Defendants have failed to demonstrate that keeping all DBS from 1984 onward is necessary to advance the compelling interest in operating the newborn screening program. Defendants even acknowledge that a minimum of 5,000 DBS are required to verify a testing instrument. ECF No. 147 at PageID.4219–20. Using Defendants' statistics, 29 instruments must be tested annually and require at least 5,000 DBS. That means the State requires at least 145,000 DBS for testing each year. Currently, the State has DBS cards (with about four blood spots per card) for four million people who were born prior to May 2010, plus cards for almost all those born after May 2010[12] in storage. Defendants have failed to demonstrate that keeping DBS cards from more than four million people in storage is a narrowly tailored process to preserve the compelling interest of testing the instruments. State Defendants' Motion for Summary Judgment for the Fourteenth Amendment storage claim will be denied as to all

[12] Thirty to forty DBS are destroyed each year in response to parent or adult child directives. ECF No. 147-23 (Kleyn Declaration).

Plaintiffs. Because there is a genuine question of material fact regarding the necessity of storing all DBS from 1984 for calibration and furtherance of the newborn screening program and whether the program is narrowly tailored to that compelling interest, Plaintiffs' Motion for Summary Judgment on the Fourteenth Amendment storage claim will also be denied.

iii.

The last Fourteenth Amendment issue here concerns the liability of Dr. Yancey. Dr. Yancey argues that he has only "serve[d] as a warehouse for DBS cards." ECF No. 149-1 at PageID.4864. He claims that the BioBank's role is narrow because "it stores the DBS cards received from the state, it pulls the blood spot cards requested by the state and sends them out as directed by the state." *Id.* at PageID.4870. Despite Dr. Yancey's attempt to distinguish his conduct from that of the State, the Sixth Circuit previously concluded that the BioBank is an arm of the State. *Kanuszewski*, 927 F.3d at 413 n.8 ("Michigan created the Neonatal Biobank to carry out the state function of storing the Infants' blood, which the state funds the Neonatal Biobank to do. The fact that the state funds the Neonatal Biobank suggests that the state's purse would be vulnerable if Plaintiffs were to recover against the Neonatal Biobank. Based on these considerations, the Neonatal Biobank is an arm of the state.").

Further, Dr. Yancey' focus on the compelling interest of the newborn screening program in his briefing, rather than the post-testing storage of the DBS, is misplaced. ECF No. 149-1 at PageID.4883–86. The initial screening itself is not in question, and in fact, the Sixth Circuit suggested that the screening itself would likely survive strict scrutiny. *Kanuszewski*, 927 F.3d at 420. Dr. Yancey has provided no argument why the post-testing research or storage of the DBS advances a compelling interest. However, he does argue that Plaintiff-parents consented to the research and storage of the DBS. As such, his Motion for Summary Judgment will be granted as

to all Fourteenth Amendment research claims, except for those involving MTL and DWL. His Motion will be denied as to the Fourteenth Amendment storage claim for all Plaintiffs.

D.

The second claim involves the ongoing storage of the DBS and Plaintiff-children's right to be free from unreasonable seizures under the Fourth Amendment. Earlier in this case, the Sixth Circuit provided,

> On remand, whether Plaintiffs consented to any aspect of Defendants' retention, storage, or future use of the blood samples will also affect whether there is an ongoing seizure in violation of the Fourth Amendment.

Kanuszewski, 927 F.3d at 425.

Similar to the Fourteenth Amendment claim, no Plaintiff-parent consented to the ongoing storage of the DBS on behalf of a Plaintiff-child. *See* Section III.B., *supra*. Therefore, the Fourth Amendment issue must be addressed as to all Plaintiff-children.

As the Sixth Circuit explained, "[i]t is apparent in the case law that the duration of a seizure affects its constitutionality." *Kanuszewski*, 927 F.3d at 424–25. The circuit also provided some guidance on what would be considered an unreasonable duration for the seizure:

> To evaluate the constitutionality of a seizure's duration, it is necessary to consider whether the duration is "reasonably needed to effectuate those purposes [justifying the seizure]." *United States v. Sharpe*, 470 U.S. 675, 685, 105 S.Ct. 1568, 84 L.Ed.2d 605 (1985). It does not seem that the health of the child justifies the state in taking any actions with respect to the blood samples after it has finished screening the samples for diseases. As discussed, Plaintiffs allege that Defendants conduct research on children's stored blood samples and seek to derive profit from the children's samples by selling them to third parties. If this is indeed Defendants' purpose in retaining the children's blood samples, then their ongoing, indefinite seizure of the samples is unreasonable. For this reason, Plaintiffs have plausibly stated a claim upon which relief can be granted, and the district court erred in dismissing their Fourth Amendment claims relating to the ongoing storage and potential future use of the blood samples. The case should proceed to discovery so that the parties may produce evidence of the state's purposes for retaining, storing, and using the children's blood samples after they have been screened for diseases.

Kanuszewski, 927 F.3d at 424–25.

Plaintiffs articulate two unconstitutional seizure theories. First, that data retention is unreasonable; and second, that the retention of the DBS itself is unreasonable. Amicus APHL argues that a seizure cannot occur unless an individual has a possessory interest in the property. ECF No. 146 at PageID.4164 (citing *United States v. Jacobsen*, 466 U.S. 109, 113 (1984)). APHL argues that "neither the Michigan legislature nor Michigan courts have established that an individual holds a property interest in biological samples extracted from a person's body. To the contrary, the Michigan statute governing newborn screening reflects a legislative determination not to grant infants or their parents a property interest in the residual DBS" because MDHHS is authorized to "develop a retention and disposal schedule for the DBS." *Id.* at PageID.4166 (emphasis omitted) However, MDHHS permits parents to request destruction of the DBS, and as of May 2010, requires parental consent for DBS to be used for research. Even though Michigan law does not explicitly provide for parental decision-making in the process, MDHHS, acting through its statutory authorization, appears to have acknowledged at least a limited property interest in the DBS to the parents by allowing them to request the destruction of the samples. Further, neither party argued that the children (or the parents on their children's behalf) do not have a property interest in the DBS themselves. The argument was solely raised by amicus.

i.

Plaintiff-children argue that the "ongoing retention of the deeply-private medical and genetic information/data in the State's files and databases, which is outside the needs of [sic] newborn screening program and without consent" violates their Fourth Amendment rights:

> What started in the hours after the infants' birth as a now-unchallengeable search of blood of evidence of a particularized (and limited) list of diseases has now resulted in a permanent extension of the seizure and unlimited searchability of the infants' medical data to an indefinite duration upon demands of Defendants rather

> than the informed desires of parents. Because, by retention of the blood spots and medical data extracted, Defendants are now always able to immediately access the private medical information of infants when such was solely obtained for an unrelated narrowly-limited purpose. This scheme of a never-ending seizure and searchability—analogous to a general warrant of infinite duration—is not reasonable under the Fourth Amendment.

ECF No. 135 at PageID.1929–31 (emphasis and footnotes omitted).

State Defendants respond that "the [Fourth] Amendment does not protect the merely subjective expectations of privacy, but only those expectation[s] that society is prepared to recognize as reasonable." ECF No. 147 at PageID.4225 (quoting *Oliver v. United States*, 466 U.S. 170, 177 (1984)). They argue retention of data is as necessary as retention of the DBS itself:

> Data is crucial for quality improvement, especially cutoff evaluations. Having data over many years is important in order to have statistical confidence. Demographic data is also important to ensure the correct DBS are retrieved in response to parent-driven requests, including sending DBS to a doctor's office to assist with diagnosis or treatment, research directed by a parent, and return or destruction of DBS.

ECF No. 142 at PageID.3361–62 (citations omitted). Mary Seeterlin, Section Manager of the Newborn Screening Section of the MDHHS Laboratory, similarly described the significance of data retention in her personal declaration:

> Retained data is crucial for our quality improvement studies, particularly cutoff evaluations. Right now, we are exploring changing the screening cutoffs for one of the disorders. This work was prompted by a false negative. We retrieved over 10 years of screening data, so we could review the effect of different proposed screening cutoffs on the number of positives and the number of false negatives. Having access to the data allows us to make evidence-based decisions and estimate the efforts of those decisions on families and clinical providers.

ECF No. 141-22 at PageID.3006.

Defendants explain that sufficient evidence exists showing that retention of some data is necessary for the NBS program to be effective. However, Defendants do not explain why it needs to retain the data indefinitely, nor why it cannot delete all relevant data when a parent asks for the DBS to be destroyed. Defendants have shown the necessity of saving data for an extended period

of time, but Plaintiffs have aptly demonstrated that the current 22-year retention policy for newborn screening testing data may be unreasonable. There remain questions of material fact regarding the reasonableness of this retention period, as well as the privacy protections that are afforded. As such, both Defendants and Plaintiffs' Motions for Summary Judgment as to the Fourth Amendment claim for retention of data will be denied.

ii.

"The [second] question," Plaintiffs state, "is whether the Fourth Amendment prohibits, as unreasonable, the retention of the blood samples after the blood spots have been fully screened for diseases and Defendants' transfer of the samples to the Biobank for ongoing storage of the samples for further use by the State and/or for sale to third-party researchers." ECF No. 135 at PageID.1931–32 (citations and emphasis omitted). Plaintiffs argue that the retention "is unreasonable because additional testing of samples authorized by Defendants (to the third-party researchers) to further obtain physiological data is a further invasion the [sic] infants' privacy interests that is not reasonable." *Id.* at PageID.1931–32 (citation and emphasis omitted). Plaintiffs continue,

> When the State provides the infants' blood samples to the Biobank, who in turn provides them to third-party for-profit and academic researchers for a fee, the infants' medical and personal privacy is both invaded and eviscerated. Defendants' need to invade this privacy is not connected with the reason for the initial extraction—to screen for newborn metabolic abnormalities. In other words, all newborn screening could be fully and completely accomplished without any need for biobanking or the post-screening long-term storage, retention, or uses (sale) of their children's blood spots containing deeply-private medical and genetic information/data. Once the testing was complete of the sample, the appropriate thing to do to protect privacy and fulfill desired newborn testing would be to immediately destroy both the samples and all the data obtained therefrom upon completion of testing.

Id. at PageID.1933–34 (emphasis and footnotes omitted).

State Defendants first argue that the retention of DBS is not a seizure "because it is done for purely medical purposes," and that even if it were a seizure, consent was obtained. ECF No. 147 at PageID.4225. Defendants explain that "[b]ecause the most significant reason DBS are retained—and the only reason DBS are retained and used without consent—is to ensure the continued efficacy of the newborn screening program, retention is primarily for medical purposes and does not implicate the Fourth Amendment." *Id.* at PageID.4226.

Alternatively, State Defendants argue that the retention is "reasonable given the benefit to, and goals of, the newborn screening program. . . To the extent the Fourth Amendment is implicated, multiple exceptions apply to the newborn screening program. First, Plaintiffs consented, as described above, to their children's DBS being available for research, which necessarily requires retention. . . . Further, the parents have the ability to terminate the seizure:

> [I]f the target of the alleged search or seizure retains the ability to stop that governmental activity, that activity was reasonable. Plaintiffs have at all times been free to change their minds and have the DBS at issue removed from MDHHS custody. Because this information is described on the signed directive, and available online or by contacting MDHHS, a reasonable person would not believe they are not free to opt out of retention.

Id. at PageID.4226–28 (citations omitted.).

Third, State Defendants argue that the special needs doctrine applies because "the program is designed to ensure public safety by protecting the health and safety of infants," not law enforcement purposes and because

> requiring a warrant for DBS every time equipment is calibrated or anonymous research is requested would be an impossible standard given the lack of a criminal purpose—there would never be probable cause of wrongdoing. Even assuming some different warrant requirement, such a step would cause significant delay and risk to the health of Michigan children, as well as place a significant burden on the legal system. Because retention is done to ensure the public health through effective newborn screening; with notice, consent for research, and the ability to remove a child's, or one's own, DBS at any time; and because of the risk to public safety and

> the lack of a purpose relating to the violation of a criminal statute, retention of DBS is reasonable and does not violate the Fourth Amendment.

Id. at PageID.4228–29 (citations omitted).

First, as discussed *supra*, Plaintiff-parents who consented to the use of their children's DBS for research do not have a Fourteenth Amendment claim for the storage of DBS. *See* Section III.B., *supra*. The same logic extends to Plaintiff-children's Fourth Amendment claim—the ongoing storage of the DBS is not a seizure if the children's parents consented to research and, implicitly, storage. However, MDHHS also keeps one DBS on hand for the parents' use, even if the parents opt out of research. Because this DBS is not kept for research purposes, nor for the continuation for the newborn screening program, consent for research is insufficient to justify the ongoing retention for this one DBS. As for the remaining Plaintiffs, consent for research was either refused or insufficiently waived by the State, so there was no consent for the storage of any of the DBS.

Second, the fact that Plaintiffs have the ability to stop the alleged seizure by a destruction request is insufficient to make the seizure reasonable. Defendants cite *United States v. Mendenhall* to support their argument that if an individual remains free to change their mind and leave, they have not been seized. 446 U.S. 544, 554 (1980) ("As long as the person to whom questions are put remains free to disregard the questions and walk away, there has been no intrusion upon that person's liberty or privacy as would under the Constitution require some particularized and objective justification."). *Mendenhall* discussed the seizure of persons and what conduct constitutes a seizure of an individual. Here, Plaintiffs' blood spots, not Plaintiffs themselves, are being retained. Further, some Plaintiffs are unaware of the seizure or their ability to end the seizure, that is, to request the destruction of the DBS. Other Plaintiffs declined to participate in research, but their DBS were still retained. State Defendants fail to offer a valid reason for the State to retain the DBS when a parent has declined to participate in research. To the extent that some DBS are

required for a specified amount of time to retest tools or design new test cutoffs, State Defendants have failed to demonstrate why a 22-year retention period is reasonable.

Third, while the special needs doctrine may apply, State Defendants have failed to demonstrate that it is reasonable and necessary to retain DBS, without consent, for twenty-two years to protect public safety. The fact that a parent or a child, once she reaches the age of 18, may request the destruction of the DBS does not change the fact that it is impossible for them to request the destruction of something they do not know exists. There is a genuine question of material fact regarding Defendants' need to store the DBS for a set period of time after the initial testing, as well as the adequacy of Defendants' effort to inform Plaintiffs of their right to decline to have their DBS stored. Plaintiffs' and Defendants Motions for Summary Judgment as to the Fourth Amendment DBS storage claim will be denied.

Plaintiffs also argue that retention of the DBS is unreasonable when the DBS are used to "generate a significant revenue stream of millions of dollars by developing pipeline [sic] of sellable products for academic and commercial researchers." ECF No. 135 at PageID.1932–33 (citations omitted). While Plaintiffs were taken at their word previously, they must now support their allegations with evidence. Defendants have clearly demonstrated that the DBS are not sold to third-party researchers and that the BioBank does not generate millions of dollars in revenue. Rather, researchers pay a fee for the administration necessary to obtain the requested DBS. ECF No. 149-5 at PageID.3966. Plaintiffs' argument that DBS are sold has no merit.

Defendant Yancey combines his arguments against the Fourteenth and Fourth Amendment claims. ECF No. 149-1. His Motion for Summary Judgment on the Fourth Amendment reasonableness claim fails for the same reasons articulated above.

IV.

In summary, Plaintiffs' Motion for Summary Judgment will be granted as to the substantive due process research claims (Count II) involving Plaintiff-parents of children DWL and MTL. It will be denied as to claims involving Plaintiff-parents of the other children. Conversely, Defendants' Motions for Summary Judgment will be denied as to the substantive due process research claims involving Plaintiff-parents of DWL and MTL and will be granted as to the claims involving Plaintiff-parents of the other children. Because the remedial implications have not received focused briefing, supplemental briefing and an evidentiary hearing, if necessary, will be directed to address the appropriate remedy for Plaintiff-parents of DWL and MTL.

Plaintiffs' and Defendants' Cross-Motions for Summary Judgment will be denied as to the substantive due process storage claims (Count II). Plaintiff-parents' fundamental right to direct the medical care for their children has been infringed, but there remain certain questions of fact material to whether Defendants' justification for the scope of their program satisfies the strict scrutiny standard articulated by the Sixth Circuit. These questions will need to be addressed at trial.

Similarly, Plaintiffs' and Defendants' Cross-motions for Summary Judgment will be denied as to the Fourth Amendment data and DBS storage claims (Count IV). There remain questions of fact relevant to whether Defendants' ongoing warrantless retention of the DBS and related data is reasonable. That question will also need to be addressed at trial.

V.

On June 28, 2021, Plaintiffs filed a motion for leave to file a DVD in the traditional manner and to accept additional evidence. ECF No. 167. Plaintiffs included a copy of a PBS documentary, "Secrets in Our DNA." They explain that it "highlights and confirms many of the concerns of

privacy raised by Plaintiffs in this case. It explores the power of information contained in DNA within our biological samples and the unintended consequences that can arise from distribution of such data with rapidly growing online databases and connections involving the same." *Id.* at PageID.5546. Defendants do not object to filing the DVD in the traditional manner but oppose the introduction of the exhibit as "untimely and irrelevant." ECF No. 168 at PageID.5555. Defendants explain that the documentary originally aired January 13, 2021—a month before Plaintiffs filed their motion for summary judgment and two months before discovery closed. Further, Defendants argue that the proposed exhibit is irrelevant because "[t]he documentary is about private companies testing consumers' DNA and references voluntary online databases of genetic information available to the public. It does not address any state-operated screening program or laboratory, let alone Michigan's newborn screening program or the Michigan Department of Health and Human Services (MDHHS) laboratory." *Id.* at PageID.5556–57.

Defendants are correct. The proposed exhibit is untimely, having been filed months after motions for summary judgment were filed. Plaintiffs also fail to explain how the video is relevant to the ongoing storage of Plaintiff-children's DBS by the state of Michigan, not a private DNA collection company. Plaintiffs' Motion for Leave will be denied.

VI.

Accordingly, it is **ORDERED** that Plaintiffs' Motion for Summary Judgment, ECF No. 135, is **GRANTED IN PART AND DENIED IN PART**. To the extent that Count II alleges a violation of Plaintiff-parents' Fourteenth Amendment right to direct the medical care of their children resulting from research conducted on the DBS, summary judgment is **GRANTED** for Plaintiffs Ashley Kanuszewski for her child DWL, and Shannon LaPorte for her child MTL and **DENIED** for Plaintiffs Ashley and Adam Kanuszewski for their children RFK and CKK, Shannon

LaPorte for her child EMO, and Lynette Wiegand for her children LRW, CJW, HJW, and MLW. To the extent that Count II alleges a violation of Plaintiff-parents' Fourteenth Amendment right to direct the medical care of their children resulting from the storage of the DBS, Plaintiffs' Motion is **DENIED**. Plaintiffs' Motion for Summary Judgment is also **DENIED** as to all Plaintiff-children for Count IV.

It is further **ORDERED** that MDHHS Defendants' Motion for Summary Judgment, ECF No. 147, is **GRANTED IN PART AND DENIED IN PART**. Defendants' Motion is **GRANTED** as to the Count II research claim brought by Plaintiffs Ashley and Adam Kanuszewski for their children RFK and CKK, Shannon LaPorte for her child EMO, and Lynette Wiegand for her children LRW, CJW, HJW, and MLW. Defendants' Motion is **DENIED** as to the Count II research claim brought by Plaintiffs Ashley Kanuszewski for her child DWL and Shannon LaPorte for her child MTL. Defendants' Motion is **DENIED** as to all Plaintiff-parents' substantive due process storage claims (Count II). Defendants' Motion is **DENIED** as to all Plaintiff-children for Count IV.

It is further **ORDERED** that Defendant Yancey's Motion for Summary Judgment, ECF No. 149, is **GRANTED IN PART AND DENIED IN PART**. Defendant's Motion is **GRANTED** as to the Count II research claim brought by Plaintiffs Ashley and Adam Kanuszewski for their children RFK and CKK, Shannon LaPorte for her child EMO, and Lynette Wiegand for her children LRW, CJW, HJW, and MLW. Defendant's Motion is **DENIED** as to the Count II research claim brought by Plaintiffs Ashley Kanuszewski for her child DWL, and Shannon LaPorte for her child MTL. Defendant's Motion is **DENIED** as to all Plaintiff-parents' substantive due process storage claims (Count II). Defendant's Motion is **DENIED** as to all Plaintiff-children for Count IV.

It is further **ORDERED** that Plaintiffs' Motion for Leave, ECF No. 167, is **DENIED**.

It is further **ORDERED** that Plaintiffs are **DIRECTED** to file supplemental briefing regarding the scope and nature of the declaratory and injunctive relief that they deem is appropriate in light of the summary judgment granted on Plaintiffs Ashley Kanuszewski and Shannon LaPorte's research claim. Supplemental briefing must be no longer than 10 pages and is due **on or before August 27, 2021**. Defendants may file a response no longer than 10 pages **on or before September 10, 2021,** or **14 days** after service with Plaintiffs' supplemental brief, whichever is earlier.

Dated: July 29, 2021

s/Thomas L. Ludington
THOMAS L. LUDINGTON
United States District Judge